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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,518	10/18/2001	Frederick W. Trombley III	VI/00-013	7226
21140	7590	07/20/2005	EXAMINER	
<b>GREGORY L BRADLEY</b> MEDRAD INC ONE MEDRAD DRIVE INDIANOLA, PA 15051				SIRMONS, KEVIN C
		ART UNIT		PAPER NUMBER
				3763

DATE MAILED: 07/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

S/

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/982,518	TROMBLEY ET AL.
	Examiner Kevin C. Sirmons	Art Unit 3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 09 May 2005.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-17, 19-22, 24-36 and 39-55 is/are pending in the application.  
 4a) Of the above claim(s) 2, 7-10, 30, 40-44 and 46 is/are withdrawn from consideration.  
 5) Claim(s) 25-29 is/are allowed.  
 6) Claim(s) 1, 3-6, 11, 12, 19-22, 31-36, 39, 45 and 47-53 is/are rejected.  
 7) Claim(s) 13-17, 24, 54 and 55 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### *Drawings*

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "954" has been used to designate a lumen, tubing and a port. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: applicant admitted that the "first port" is unnumbered. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: first and third ports (Claim 11); a low-pressure fluid delivery system (claim 11).

All objections are a direct result of applicant's amendments and arguments.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-6, 11, 19-22, 47 and 50-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Palestrant U.S. Pat. NO. 5,002,528.

Palestrant discloses an injector system comprising: an powered injector (22 and line entering port 18); a pressurizing chamber in operative connection with the powered injector (interior of 22 and/or 20); a fluid path in fluid connection with the pressurizing chamber and a source (12) of injection fluid (the entire fluid pathway of the system of fig. 2); a manual control device (25) in operative connection with the powered injector,

the manual control comprising at least one actuator (the piston of the plunger (not shown) the manual control device comprising a preprogrammed injection mode (col. 2) wherein depression of the actuator causes the powered injector to deliver a preprogrammed injection of injection fluid and wherein the manual control device is adapted to stop an injection procedure if no force is applied to the actuator (the piston of the plunger is fully capable of stopping the injection procedure if no force is applied to the actuator); Note: Claim 1 (2<sup>nd</sup> time), is so broad that Palestrant has at least several different interpretations because an injector has no structure, the pressurizing chamber has no structure, the fluid path has no structure and a manual control has very little structure; as to claim 3, the device of Palestrant is fully capable of performing applicants function; as to claim 5, (60 and/or 68); as to claim 6, (stopcock 20); As to claim 11, (see above rejections and fig. 2); as to claims 19, (see above rejections); as to claim 20 and 21, the pressure can be low or high depending on the user); as to claim 22, (see side rings); as to claim 47, (20); as to claims 50-53, (fig. 2)

Note to applicant: Powered and pre-programmed are extremely broad and carry very little patentable weight.

Claims 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Woelpper et al U.S. Pat. No. 55,69,208.

Woelpper discloses a pressurizing device (20, 18, and 58); a low pressure fluid delivery system (figs. 2-8); a pressure isolation mechanism (64) having a first-third port (figs. 2-8); note: the valve of Woelpper is fully capable of performing the function as set forth in claim11; as to claim12, (68, 72).

Claims 1, 3-6 and 47-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Duchon et al U.S. Pat. No. 6,221,045

Duchon discloses an injector system comprising: an powered injector (10); a pressurizing chamber (18) in operative connection with the powered injector; a fluid path in fluid connection with the pressurizing chamber (figs. 1 and 2) and a source (22) of injection fluid; a manual control device (12 and 14) in operative connection with the powered injector, the manual control comprising at least one actuator (based on applicant's own admission (see arguments) a switch can be regarded as an actuator. Therefore, the examiner regards (56, 62 and 64 as the actuators) the manual control device comprising a preprogrammed injection mode (12 and entire specification) wherein depression of the actuator causes the powered injector to deliver a preprogrammed injection of injection fluid and wherein the manual control device is adapted to stop an injection procedure if no force is applied to the actuator (12 and entire specification); as to claims 4-6, 47-50, (figs. 1 and 2)

Claims 31-33, 35-36 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Genese U.S. Pat. No. 4,243,031.

Genese discloses a fluid path set comprising: a multi-patient use section (fig. 1); a per-patient use section (10 to 25); first port (fluid entrance area); second port (fluid exit area) and a pressure isolation port (as to fig. 1, 41 and/or entrance to 35; as to figs. 4 and 5, first port (fluid entrance areas), second port (fluid exit area); and a pressure isolation mechanism (any area where the valve closes of the port); as to claim 32, (16), as to claim 33, (fig. 1); as to claims 35-36, (figs. 2-5); as to claim 37, (fig. 1);

as to claim 38, (fig. 1); as to claim, 39, (fig. 1); as to claim 45, (21).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31-36 and 39 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5, 11-15 and 18-22 of copending Application No. 10/237,139. Although the conflicting claims are not identical, they are not patentably distinct from each other because are directed to pressure isolation mechanism and fluid delivery system.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Allowable Subject Matter***

Claims 13-17, 24, 54 and 55 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 25-29 are allowable over the prior art of record.

***Response to Amendment***

***Claim Rejections - 35 USC § 112***

Applicant has specifically pointed out what he regards as the pressurizing chamber in a non-elected species. Therefore, the rejection is withdrawn.

Applicant has specifically pointed out in the specification what he regards as the actuators. Therefore, the rejection is withdrawn.

Applicant has specifically pointed out in the specification what he regards as a low-pressure fluid delivery system. Therefore, the rejection is withdrawn and an objection replaces the rejection because applicant has no antecedent basis for the claimed language in the specification.

Applicant has amended the claim to overcome the lack of antecedent basis for "the syringe pump." Therefore, the rejection has been withdrawn.

Applicant has amended claim 32 to overcome the rejection. Therefore, the rejection has been withdrawn.

***Response to Arguments***

Applicant's arguments with respect to claims 1, 3-6 and 11 have been considered but are moot in view of the new ground(s) of rejection.

As to Woelpper, claims 11 and 12, the stopcock valves of Woelpper clearly disclose a valve that is normally biased because normally biased is extremely broad thus carries very little patentable weight. What does normally biased mean? Anyhow, Stopcock valves that must be manually turned from one position to another position to allow fluid flow along a different path through the stopcock valve is not excluded from the claims. Normally, biased simply means favoring one side than the other. Accordingly, claim 11 is anticipated by the teachings of Woelpper. The Examiner has without a doubt taken into consideration the broad language in claim 11 stating that the pressure isolation mechanism includes a valve that is normally biased to a first state and is switchable to a second state under fluid pressure. Again, the device of Woelpper is fully capable of being switchable to a second state under fluid pressure.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the first (i.e., injector) port is continuously connected to the third (i.e., patient) port are not recited in the rejected claim(s).

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Note: Applicant failed to place claim 19 in proper condition for allowance. (See prosecution history)

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Sirmons whose telephone number is 571-272-4965. The examiner can normally be reached on Monday-Friday 6:30-4:00 ALT FRI.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin C. Sirmons  
Primary Examiner  
Art Unit 3763

*Kevin C. Sirmons*  
7/3/05